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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,369	04/20/2004	Baldomero M. Olivera	2314-278	4193

6449 7590 01/04/2007

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	01/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 01/04/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/827,369	OLIVERA ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The restriction requirement in the Office action of July 7, 2006 is withdrawn and is replaced by the restriction requirement as indicated below. In their response of December 7, 2006, Applicants have clarified that several residues in SEQ ID NO: 1 can be missing or present, and, therefore, SEQ ID NO: 1 reads on all of the sequences in the group of SEQ ID NOS: 2-13. As a result, as discussed below, Applicants are required to elect one definite sequence that is used in a method of treating one disease.

SEQ ID NO: 1 does not represent a proper Markush group because it recites an enormous number of sequences whose primary structures vary very widely. These sequences are of different lengths, because there is a first gap between the N-terminal portion of the sequences and Xaa_2 and a second gap between Xaa_8 and the C-terminal portion of the sequences. The second gap is of variable length. Any amino acid that is present can be any amino acid, naturally occurring or unnaturally occurring. Thus, the amino acid composition of these sequences varies enormously. Also, because of the gaps and unlimited substitutions, SEQ ID NO: 1 does not describe any of the disclosed conotoxin polypeptides. Consequently, Applicants are required to elect a method of using one definite sequence as indicated below, and SEQ ID NO: 1 will be examined to the extent that it reads on the elected sequence.

Restriction to one of the following inventions is required under 35 U.S.C. 121.

I. Claims 1-3 and 9-15, drawn to a method of treating a cardiovascular disorder, comprising administering a therapeutically effective amount of one polypeptide from the set of SEQ ID NOS: 2-13, classified in class 514, subclass 13 or 14.

II. Claims 1, 2, 4 and 9-15, drawn to a method of treating a gastric motility disorder, comprising administering a therapeutically effective amount of one polypeptide from the set of SEQ ID NOS: 2-13, classified in class 514, subclass 13 or 14.

III. Claims 1, 2, 5 and 9-15, drawn to a method of treating urinary incontinence, comprising administering a therapeutically effective amount of one polypeptide from the set of SEQ ID NOS: 2-13, classified in class 514, subclass 13 or 14.

IV. Claims 1, 2, 6 and 9-15, drawn to a method of treating nicotine addiction, comprising administering a therapeutically effective amount of one polypeptide from the set of SEQ ID NOS: 2-13, classified in class 514, subclass 13 or 14.

V. Claims 1, 2, 7 and 9-15, drawn to a method of treating a mood disorder, comprising administering a therapeutically effective amount of one polypeptide from the set of SEQ ID NOS: 2-13, classified in class 514, subclass 13 or 14.

VI. Claims 1, 2 and 8-15, drawn to a method of treating small cell lung carcinoma, comprising administering a therapeutically effective amount of one polypeptide from the set of SEQ ID NOS: 3-12, classified in class 514, subclass 13 or 14.

VII. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 5, classified in class 514, subclass 13.

VIII. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 7, classified in class 514, subclass 14.

IX. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 8, classified in class 514, subclass 13.

X. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 9, classified in class 514, subclass 13.

XI. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 12, classified in class 514, subclass 13.

XII. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 13, classified in class 514, subclass 14.

The inventions are distinct, each from the other because of the following reasons.

Inventions I – XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, each of groups I-VI is drawn to a method of treating a different disease. Groups VII-XII are drawn to methods of treating a genus of diseases, but in each method, a different therapeutic compound is administered. All of therapeutic compounds in groups I-VI are different from all of the therapeutic compounds in Groups VII-XII. Therefore, all of these inventions are patentably distinct.

Should one of Groups I-VI be elected, as discussed above, further restriction is required. Applicants are required to elect one definite sequence from the set of SEQ ID NOS: 2-13.

The searches for any one group are not required for and are not coextensive with the searches for any other group, thereby creating an undue burden of search and examination. The results from a search of each of these groups have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement.

As discussed above, Applicants must choose **ONE** polypeptide from among those claimed as indicated in the different groups above. Each polypeptide sequence is a distinct invention requiring separate searches. These are NOT species. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, each of these polypeptides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Should applicant traverse on the ground that these different compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2006-12-21

Rosanne Kosson

Jon Weber
Supervisory Patent Examiner